MAQUET
GETINGE GROUP

510(k) Summary
(as required by 21 CFR 807.92)

SEP 10 2012

510(k) Number:	Unknown
Date Prepared:	August 23, 2012
Device Owner:	MAQUET Cardiovascular LLC 45 Barbour Pond Drive Wayne, New Jersey 07470
Contact Personnel: **Title:** **Email:** **Phone:**	Marylou Insinga Regulatory Affairs Specialist II marylou.insinga@maquet.com 973-709-7442 **Fax:** 973-807-1658
Trade Name:	HEMASHIELD Woven Vascular Grafts
Device Generic Name:	Vascular Graft Prosthesis
Classification:	According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.
Predicate Device:	HEMASHIELD Woven Vascular Grafts
Device Description:	The HEMASHIELD Vascular Grafts are Woven Double Velour polyester grafts impregnated with highly purified collagen. The HEMASHIELD Vascular Grafts are designed to reduce bleeding at implant and thereby eliminate the operative preclotting step. The collagen is designed to be gradually resorbed by the patient. In addition to collagen, the grafts also contain glycerol as a softening agent.
Indications for Use:	The HEMASHIELD Vascular Grafts are indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prostheses are also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.
Technological Characteristics	The proposed HEMASHIELD Vascular Grafts and the predicate HEMASHIELD Vascular Grafts are similar with respect to the following: • Identical materials and finished device characteristics • Identical indication for use • Identical packaging, sterilization and shelf life

The proposed HEMASHIELD Vascular Grafts and the predicate HEMASHIELD Vascular Grafts are different with respect to the following:

- An alternate method for the collagen coating process was used in manufacturing the proposed devices.

This difference is not considered a technological difference and is substantially equivalent to the predicate HEMASHIELD Vascular Grafts.

Safety and Performance:

Bench testing was performed to support a determination of substantial equivalence. The device was qualified through the following tests:

- Water Permeability
- Longitudinal Tensile Strength
- Factory Anastomotic Strength
- Burst Strength
- Usable Length
- Relaxed Internal Diameter
- Pressurized Internal Diameter
- Wall Thickness
- Suture Retention Strength (Suture Pull Out)
- Guideline

The results of these non-clinical tests meet the specified acceptance criteria and are substantially equivalent to the predicate device.

No new safety or performance issues were raised during the testing regimen.

Conclusion:

Based on the Indication for Use, technological characteristics and performance testing, the HEMASHIELD Vascular Grafts have been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 10 2012

Maquet Cardiovascular, LLC
% Marylou Insinga
45 Barbour Pond Dr.
Wayne, NJ 07470

Re: K122612
Trade/Device Name: Hemashield Woven Double Velour Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: Class II
Product Code: MAL
Dated: August 23, 2012
Received: August 27, 2012

Dear Marylou Insinga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HEMASHIELD Vascular Grafts 510(k) August 2012

Indications for Use

510(k) Number (if known): K122612

Device Name: HEMASHIELD Vascular Grafts

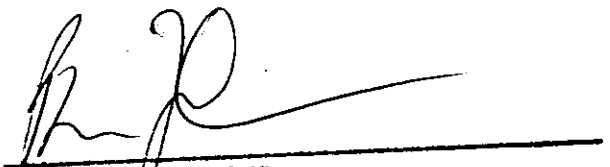
Indications For Use:

The HEMASHIELD Vascular Grafts are indicated for use in the replacement or repair of arteries affected with aneurysmal or occlusive disease. The prosthesis is also recommended for use in patients requiring systemic heparinization prior to, or during, surgery.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122612